



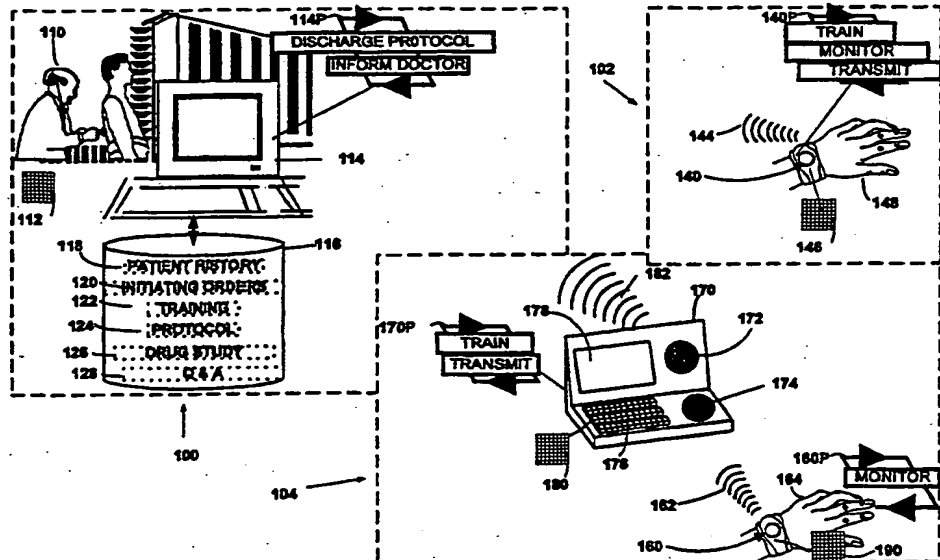
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G06F 19/00		A1	(11) International Publication Number: WO 98/50873
			(43) International Publication Date: 12 November 1998 (12.11.98)
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(22) International Filing Date: 1 May 1998 (01.05.98)			
(30) Priority Data: 60/045,436 2 May 1997 (02.05.97) US 60/081,369 10 April 1998 (10.04.98) US		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications US 60/045,436 (CIP) Filed on 2 May 1997 (02.05.97) US 60/081,369 (CIP) Filed on 10 April 1998 (10.04.98)		Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.	
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(54) Title: CYBER MEDICINE DISEASE MANAGEMENT

(57) Abstract

The subject health monitoring system is designed to supplement in an embodiment of the invention the health care efforts in caring for patients confined to their homes. The system may also be utilized within a facility such as a nursing home for monitoring patients within the home. The system integrates components distributed between a hospital and/or a central monitoring office to provide improved monitoring of these patients. The system provides for the translation of initiating orders into a computerized format. The system further provides for the programming of a patient monitoring unit at the remote site with the specific protocols consistent with the diagnoses of the doctor, as indicated on the initiating order. The system further provides for computerized training and prompting of the patient to assure their compliance with the initiating orders. Additionally, the system provides for intelligent communication between the remote site and the central office when appropriate. The system provides for the transmission of relevant data from the remote site to the central office when a critical event occurs. The system also provides for notification and graphical presentment to the doctor of trending of the patients biometric parameters. The trending parameters computed and presented to the doctor are disease specific, thus making for a more timely response. Finally, the system provides for the accumulation of a statistically normalized database correlating various medications as to their efficacy, duration, and side effects.



CYBER MEDICINE DISEASE MANAGEMENT

BACKGROUND

Field of the Invention

This invention relates to a method and apparatus for monitoring a subject.
More particularly this invention relates to monitoring a patient at a remote site from
5 a central station.

Prior Art

Modern society with its improvement in living conditions and advanced
health care has brought about a marked prolongation of life expectancy. This
change has resulted in a dramatic and progressive increase in the geriatric
10 population. A large percentage of the geriatric population needs continuous general,
as well as medical, supervision and care. For example, supervision of daily
activities such as dressing, personal hygiene, eating and safety as well as supervision
of their health status is necessary. Furthermore, the relief of loneliness and anxiety
is a major, yet unsolved, problem that has to be dealt with. These and other facets of
15 the management of the ever increasing geriatric population have yet to be
successfully
addressed and solved.

The creation of retirement facilities and senior housing, as well as other
geriatric facilities, provide only a partial solution to the problems facing the geriatric
20 population. The geriatric population, a constantly increasing fraction of society, has

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care for these persons with acute or chronic illnesses has gained in popularity as institutions sited care has receded.

Except for limited supervised housing arrangements, non-medical home care is carried out either by the patient's family or by nonprofessional help. The monitoring equipment at home care facilities is usually minimal or nonexistent. The patient has to be transported to the doctor's office or other diagnostic facility to allow proper evaluation and treatment. Patient follow-up is done by means of home visits by nurses which are periodic in nature, time consuming, and generally very expensive. A visiting nurse can visit 5-6 homes per day. The visits are limited in time and can usually not be carried out on a daily basis to an individual patient. Moreover, a visiting nurse program provides no facilities for continuous monitoring of the patient and thus, no interventional care, except in fortuitous circumstances in times of emergency. The remainder of day after the visiting nurse has left is often a period of medical isolation and loneliness for the elderly patient.

The existing home care nursing organizations divert skilled nurses, a scarce commodity, from the hospital environment and use them in a highly inefficient manner due to travel time to widely dispersed patients and the lack of sophisticated diagnostic capabilities in the patients' home. Clearly, the practice of visiting nurses is constrained.

These above considerations, which apply to the general population, as well as the spiraling cost of hospital care have led to a dramatic increase in the use of outpatient care as a treatment modality.

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Lately, transtelephonic ECG surveillance has been gaining in importance. This system uses small ECG transmitters which allow the transmission of the patients ECG over any telephone line to a diagnostic center. This on-line information system is operative 24 hours a day, 365 days a year. The patient is in direct contact with a highly trained team that can intervene at any time and make real time decisions. The drawback of this system is its communication system, which does not lend itself to prolonged monitoring sessions and does not allow for visual observation of the subject.

A home medical surveillance system is described in U.S. Pat. No. 4,838,275, issued to Lec. This system involves the generation and transmission of health-parameter signals from a patient's home to a central station. However, the described system envisions only two way voice communication between the patient and the observer at the central station. This system does not provide for interactive visual communications between the patient and health care provider, and thus lacks a principal feature and advantage of the present invention.

U.S. Pat. No. 4,524,243, issued to Shapiro discloses a personal alarm system in which a warning signal is sent to a central monitoring station if the patient's activity level becomes inactive, such as in the case of a medical emergency. This technology is limited in its diagnostic and therapeutic value, and does not, in and of itself, provide for interactive voice or visual communication between the patient and the physician.

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Nursing Center) system described in U.S. Pat. No. 5,084,828, issued to Kaufman et al. This patent includes a robot capable of monitoring the patient's vital signs, reminding the patient of his or her medications, dispensing them in due time, and contacting a control center for routine follow-up as well as in emergency situations. This device is generally an unsatisfactory solution to the problem of at-home patient

5 monitoring because it is extremely expensive, cumbersome, and lacks interactive communication capabilities between the patient and their physician.

The complex robotic units and home computer are impressive in their capacity, they but lack the human contact which is so important in effective geriatric care. The patient's interaction with a machine, as sophisticated as it may be, will

10 always be inferior to the direct human contact. Moreover, these systems are very expensive and will in the foreseeable future be available to only a very small number of patients who can afford them. Moreover, the older population does not adjust easily to computers

and robots, and mistakes in their use are frequent. Maintenance and problems and

15 the difficulty in programs in the computerized system make the upkeep more complex. Thus, the currently available techniques for providing home patient monitoring, particularly of the elderly, leave much to be desired.

Additional facts support development of an improved home health care system especially for a geriatric population. For example, falls are a major health

20 problem among the elderly, causing injury, disability and death. One third (some studies suggest half) of those over the age of 65 suffer at least one fall each year.

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inexpensive procedure for undertaking such diagnosis or investigating such predisposition in a large patient population, wherein the kinematic condition of the patient can be investigated or where the appearance, and reflex activity of the patient can be investigated with ease.

Accordingly, there is a need for improved methods and devices for (remote
5 monitoring patients.

SUMMARY OF INVENTION

The invention has the benefit of allowing multiple remote sites to continuously monitor patient data. Each of the remote sites is equipped with a user configurable decision making process to determine when to transmit patient data.

10 When the programmable processor that is detecting patient data determines that one or more of the vital signs being monitored exceeds a threshold determined by a position then the data for that vital biometric parameter as well as the data concurrently obtained from the monitoring of other biometric parameters is retrieved from the respective storage buffers and transferred to the monitoring site. This

15 selective broadcasting only under unstable or alarming conditions from plurality of patients to receiving site assures that only those patients requiring attention are broadcasting data to the receiving site. When an alarm condition occurs the

BRIEF DESCRIPTION OF THE DRAWING

In the detailed description of presently preferred embodiments of the present invention which follows, reference will be made to the drawings comprised of the following figures, wherein like reference numerals refer to like elements in the various views and wherein:

5 FIG. 1 is an overall functional block diagram of a first embodiment of the patient monitoring system of the present invention;

 FIG. 2 is a hardware block diagram of the portable patient monitor shown in FIG. 1 for monitoring and training a patient at a remote site and for transmitting data directly from the remote site to a central office when appropriate.

10 FIG. 3 is a hardware block diagram of the portable patient monitor shown in FIG. 1 for monitoring a patient at a remote site and for transmitting patient biometric parameters to a patient monitoring computer at the remote site.

 FIG. 4 is a hardware block diagram of the patient monitoring computer shown in FIG. 1 at the remote site.

15 FIG. 5 shows the software modules associated with the central office and remote site.

 FIG. 6 shows an embodiment of the data structure associated with discharge orders for a patient.

 FIG. 7A-C show the data structures associated with the disease specific
20 protocol records of the current invention.

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DESCRIPTION OF THE PREFERRED EMBODIMENT

The patient health monitoring system is designed to supplement the health care efforts in caring for patients confined to their homes. The system may also be utilized within a facility such as a nursing home for monitoring patients within the home. The system integrates components distributed between a hospital and/or a central monitoring office to provide improved monitoring of these patients. The system provides for the translation of physician orders: including traditional discharge, or patient transfer orders, into a computerized format. In a healthcare setting an initiating order may be generated by a physician for a patient in a health care facility such as a hospital or nursing home, or for a patient leaving such facilities, or for a patient in an ambulatory setting. As will be obvious to those skilled in the art other settings exist for initiating orders, including non-medical settings such as biologic monitoring of normal subjects both human and animal. The system further provides for the programming of a patient monitoring unit at the remote site with the specific protocols consistent with the diagnoses of the doctor, as indicated on the initiating order. The system further provides for computerized training and prompting of the patient to assure their compliance with the initiating orders. Additionally, the system provides for intelligent communication between the remote site and the central office when appropriate. This latter capability reduces the time required at the central office to monitor patients, yet assures that critical events occurring during patient monitoring will not be overlooked. The system provides for the transmission of relevant data from the remote site to the central office when a

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the remote monitoring system facilitates a reduction in the size of the portable patient monitoring unit by packaging several functions in the patient monitoring computer.

Computer 114 may access a plurality of databases in storage device 116. Six databases are shown specifically: patient history database 118, initiating order
5 database 120, training database 122, protocol database 124, drug study database 126, and question & answer ("Q&A") database 128. The patient history database contains records pertaining to the medical history of various patients treated at the Hospital/Central Monitoring Office 100. Such records may be created by health care
10 workers during their care of the patient. The initiating orders database contains records with information corresponding to the initiating orders 112. The discharge order may be used by the patient monitoring system in generating a protocol record that may be used in the monitoring of the patient according to the invention. The
initiating order also serves as a starting point for further treatment plans by health care workers. The training database contains records such as audio clips, short
15 visual displays or films, and text-based messages. These records contain information that instructs patients how to use the various sensors which are part of or connected to the portable patient monitor at the remote site. The drug study database contains records that relate to use of data generated through operation of the patient health monitoring system for developing new or improved drugs. The Q&A
20 database includes records with predetermined questions appropriate for a specific disease state or for response to a particular event detected by the monitoring system.

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transmitted to a remote monitoring system. Typical management records include information such as types and frequency of medication to be administered, types of sensors to be used, training files and Q&A files that might be appropriately associated with carrying out the protocol.

The management records are downloaded to remote monitoring systems,
5 such as the one-piece and two-piece systems. In the case of patient monitoring system 140, processes 140P are implemented by portable monitoring device 140 for monitoring the patient, for training the patient in the use of monitoring devices, or sensors for selecting the time of day to monitor, and for deciding when to transmit data from the remote site to the central office. All of these processes may be
10 implemented on a disease specific basis, each with its own different monitoring protocol. Results from the monitoring carried out by the portable patient monitor are transmitted 144 back to the Hospital/Central Monitoring Office 100 by processes 140P. The portable patient monitor may buffer the results until it is appropriate to transmit them. Likewise, at site 104, portable patient monitor 160 implements
15 processes 160P to monitor the patient's condition, and to transmit the monitoring results to the patient monitoring computer (PMC) 170, as suggested by element 162. File 190 contains code to direct these activities. The patient monitoring computer implements processes 170P to display training information and to transmit 182 back to the Hospital/Central Monitoring Office 100 the results of the monitoring. The
20 patient monitoring computer may buffer the results until it is appropriate to transmit

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the biometric parameters being monitored by sensors 242 and 244. These sensors may be selected according to the patient's situation, but often will include such baseline parameters as blood pressure, pulse, temperature, and respiratory rate. This data is continuously stored in buffers 216 and 218. The data in these buffers is continuously monitored according to reprogramable signal limits stored in memory units 220 and 222. When microprocessor 202 detects that any single limit or combination of limits in any arrangement according to the management record is triggered, then the data in all buffers is passed to cellular transceiver 204 for wireless transmission to the central monitoring office.

When this packet of data is received by the central monitoring office, additional data may be requested from the remote site. The user may be requested to confirm the severity of the bodily dysfunction. Patient confirmation may be sent by the patient, in this case by enabling switch 246 to key input 208, and wirelessly transmitted via transceiver 204 to the central monitoring office. This data along with the biometric parameter data is included in a packet available for the health care worker who is made aware of this packet. At appropriate times, such as upon the occurrence of a triggering event, training information may be displayed for the patient using display 240. Such training information is contained in the training record which forms part of the management record. The training information may show the patient how to use the device. The training information may show the patient how to hook up additional sensors to the portable patient monitoring device,

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interface 408, cellular transceiver 404, storage device 424, video/audio output 440, video input 442, signal unit 430, short range transmitter 432, and short range receiver 434. Buffer 416 comprises individual buffers 416 and 418 for data received from sensors contained in the portable patient monitor, shown in FIG 3. Limit memory 412 comprises limit memories 420-422 to store established values for triggering events.

In operation this system performs as follows. Storage device 424 contains within it a management record file 180 received from the central monitoring station shown in FIG. 1. The management record includes program codes for: sensors to read, when to take readings of those sensors, information as to what levels of sensor readings or times, etc., might serve as triggering events, and also training and Q&A files for display by audio output device 440, or video output 440 under appropriate circumstances. The management record file may be updated as desired by transmitting information from the central monitoring station, which is received by cellular transceiver 404. Portions of the management record relating to monitoring are sent to the portable patient monitor 160 via short range transmitter 432. These instructions serve to guide the operation of the portable patient monitor, as discussed above in FIG. 3. In return, the portable patient monitor sends signals that are received by short range receiver 434 and are processed by signal unit 430. These signals are from devices in the portable patient monitor, and may be selected according to the patient's situation, but often will include such baseline parameters as blood pressure, pulse, temperature, and respiratory rate. This data is continuously

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also outputs and downloads a management record 582 based on the information contained in the various databases and initiating orders. The translation module may receive an uploaded event record as an input from portable patient monitor . The translation module then outputs information from the uploaded event record to notification module 502. The notification module then may output this information to graphical user interface module 504, which displays the information on display 506 for a health care worker to see.

Control module 554 receives a downloaded management record 582 as an input. The control module then outputs the triggering event portion of the record to the event module 550, and the training portion of the record to training module 552. The training module outputs the training portion of the record upon instructions to do so from the control module. The control module additionally interfaces with timer module 556 to track time. The control module interfaces with the sensing module to switch it to the appropriate ones of the sensors 590-594. The control module also receives input from sensing module 560 and from recording module 558, regarding input from the selected ones of sensors 590-594. Sensing module 560 receives input from sensors 1-3, (elements 590, 592, and 594, respectively) and then outputs the information to both the control module and the recording module. The recording module stores the information from the sensing module and transmits it to the control module at an appropriate time.

In operation, translation module 500 receives initiating order 112, stores it in the initiating order database 120, and then assembles a management record based on

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FIG. 6 shows a plurality of records, labeled 600, 602, and 604, that correspond to initiating orders. Physician orders, e.g. initiating orders may be generated by a patient's physician or assistant and may be generated at the time a patient is released from a hospital or other care setting. Each initiating record may contain patient information in fields 610, diagnosis in field 612, and medication information in fields 614. As will be obvious to those skilled in the art the diagnosis field may include more than one diagnosis.

As shown in initiating record 600 patient information field 610A includes name (John Smith), age (66), sex (male), residence (11 Oak Street), Insurance (Everlast), and physician name (Dr. Fine). Diagnosis field 612A contains the diagnosis (diabetes) for the patient who has been described in patient information field 610A. Medication fields 614A contains the prescription from the patient's physician to describe a medication and its dosing regimen for the patient. In the medication fields, inputs are accepted for type of medication (insulin), route of administration (subcutaneous), the name of the medication (NPH), the frequency of administration (2x/daily), and the dose per administration (20 Units). Additional medications may be included in the initiating orders in similar formats.

Initiating records 602-604 contain similar information to initiating record 600, but for Lucile Jones, and Donna Hengst, respectively. In record 602, the patient information for Lucille Jones is contained in patient information field 610B. The diagnosis for Lucile Jones (congestive heart failure) is contained in diagnosis field 612B. The appropriate medication for the patient (ACE inhibitor) is contained in

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sensor B, which is in this case a finger prick blood glucose test. Also contained in field 716A, in a similar fashion to field 714A, are various values of results from the sensor which will trigger different responses from the portable patient monitoring system. Baseline biometric field 718A contains information about whether the patient is to be monitored for baseline biometric parameters such as: blood pressure, pulse, temperature and respiration rate. Display fields 720A contain information about how to display information accumulated during the monitoring operation of the patient health system so as to allow for focused rapid physician response to an event detected by the remote patient monitoring system. Q&A field 730A contains a file that has various questions that could be accessed in the course of obtaining subjective information from the patient during the monitoring process. Training field 732A contains training files that can be used to train the patient in the use of monitoring equipment, or the attachment of existing or additional biometric sensors. Random field 734A contains information about when to randomly include an additional monitoring of the patients biometric parameters. By requiring for example, each patient in the remote population to perform an additional test, e.g. finger prick and blood sample, information on the efficacy and durability of a specific drug can be obtained. This information is obtained through the aggregation of information from each member of the patient population under the control of the central monitoring station.

Elements 714A-716A contain information instructing the remote monitoring equipment how to respond to particular ranges of the biometric parameters being

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time field, 712B, contains information about both the frequency and the time period in the day in which to monitor for the primary biometric. In this case, fluid retention is to be monitored once daily, at 9:00 a.m. Sensor field 714B describes a sensor A and a sensor B to be used, and also includes information about what received values of sensor A-B may be considered to be triggering events. Field 716B describes

5 sensor C, which is in this case a blood oxygen test. Also contained in fields 714B-716B are various values of results from the sensors that will trigger different responses from the portable patient monitoring system. Baseline biometric field 718B contains information about whether the particular biometric is actually enabled or not enabled, instructing the remote monitoring equipment as to whether or not to

10 monitor this particular biometric. Display fields 720B contain information about how to display information accumulated during the monitoring operation of the patient health system. Question and answer field 730B contains a file that has various questions that could be accessed in the course of obtaining subjective information from the patient during the monitoring process. Training field 732B

15 contains training files that can be used to train the patient in the use of monitoring equipment. Random field 734B contains information about when to randomly include an additional test, for drug study purposes.

Elements 714B and 716B contain information instructing the remote monitoring equipment how to respond based on the particular condition. For

20 example, sensor A is employed for testing the patient's weight and sensor B is employed for measuring the patient's edema. In the setting of congestive heart

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monitored four times daily, once at 8:00 a.m., 12:00 noon, 6:00 p.m., and 10 p.m.

Sensor A field 714C describes a sensor to be used, and also includes information about what received values of sensor A may be considered to be triggering events.

Also contained in field 714C are various values of results from the sensor which will trigger different responses from the portable patient monitoring system. Baseline

5 biometric field 718C contains information about whether the particular biometric is actually enabled or not enabled, instructing the remote monitoring equipment as to whether or not to monitor this particular biometric. Display fields 720C contain information about how to display information accumulated during the monitoring operation of the patient health system. Question and answer field 730C contains a
10 file that has various questions that could be accessed in the course of obtaining subjective information from the patient during the monitoring process. Training field 732C contains training files that can be used to train the patient in the use of monitoring equipment. Random field 734C contains information about when to randomly include an additional blood pressure test, for drug study purposes.

15 Element 714C contains information instructing the remote monitoring equipment how to respond based on the particular condition. For example, if sensor A is employed for testing the patient's blood pressure and the result is a systolic blood pressure less than 90 mm Hg then the patient is instructed to recheck her blood pressure in one hour. However, if the result is either systolic greater than 200
20 or less than 80, then the monitoring system plays a question and answer file contained in field 730C, and notifies the central monitoring station with an

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corresponds to the point at which the biometric parameter e.g. the signal 850 has returned to an amplitude below upper threshold 852. Of course it is possible that the biometric parameter indicated by signal 850 would not return below the upper limit 852 in which case data would be locked in a continuous transmit condition until such time as the patient received attention or the biometric parameter being

5 monitored returned below the upper threshold, indicated by T3. For an appropriate amount of time in this case indicated as the interval between T3 and T4 after a given biometric parameter triggering an alarm condition returns below the threshold condition which caused the alarm condition, data will continue to be transmitted in real time to the central office. At time T4 data may cease to be transmitted, having

10 normalized for a sufficient interval. Alternately, data may continue to be transmitted until a physician indicates otherwise. As will be obvious to those skilled in the art, the reprogramable feature of the current invention and the programming feature itself allows any combination of upper and lower limits at any number of biometric parameters in any combination or grouping to be the condition upon which an alarm

15 condition should be generated. For example, a rise in heart rate to a certain level unaccompanied by a corresponding fall in some other biometric parameter such as blood pressure may not, according to the physician, be a cause for triggering an alarm condition. This more complex thresholding condition is stored in limit

20 memory. As will also be obvious to one skilled in the art, an alarm condition need not merely correspond to the amplitude of a biometric parameter but might

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conflict is brought to the attention of a physician so that they may resolve it before programming the remote monitoring system.

In the event there is no conflict between the physician initiating and the protocol record, or in the event that a physician has modified an existing protocol record to harmonize it with his/her initiating orders, then control is passed to process 914. In process 914 any files such as Q&A and/or training files associated with the protocol record are retrieved from respectively databases 122 and 128 (see FIG. 1). Control is then passed to process 916. In process 916 statistical information gathering processes are implemented for retrieving from this patient additional information useful for the aggregate characterization of the drug being utilized to treat this patient. This may take the form of an additional time of day at which to monitor the patient. This time may correspond to 1/2 hour after prescription dosage. If another patient treated with the same drug is monitored at 1 hour after prescription dosage, and so forth, a complete time weighted study of the drug efficacy and duration can be created from the aggregation of a plurality of patients. This time will be placed in field 734 (see FIG. 7A-C). Control is then passed to process 918. In process 918 the management record including the Q&A and training records and the code associated with implementing the protocol record retrieved in process 906 are downloaded to the remote site. Control is then passed to decision process 920.

In decision process 920 a determination is made as to whether an event record has been received from a remote site. In the event that determination is in the negative, control is returned to decision process 902 for the processing of the next

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FIG. 1. The process commences at 1000 where data is being obtained from the sensors processed and put into FIFO buffers corresponding to the respective sensors. The data in these buffers is continuously compared with the limits and limit conditions stored in limit memory in process 1002. Control is then passed a decision step 1004 in which a determination is made on the basis of the comparison as to whether an alarm condition corresponding to a limit, or a set of limits programmed by the physician has been exceeded. In the event this determination is in the affirmative then control is passed to decision process 1006. In process 1006, the transceiver begins transmitting not only the historical data contained in the buffers, but also a real time transmission of all sensor data to the central office. Control is then passed to process 1008 in which an on-going monitoring of limits is made. These may be the limits as discussed in connection with FIGS. 7A-C, or may be different set of physician programmable limits set by a physician by a transmission from the central office. These not need be the same limits. Control is then passed to decision step 1010 in which a determination is made as to whether the cease alarm condition has been reached. This process is optional as in certain embodiments it may not be appropriate to cease transmitting at all even after biometric parameters have returned to normal. The cease alarm condition could be input by a physician from the central office, or from an visiting nurse present at the remote site, or could be automatically generated through a return of the patient's biometric parameters to a prolonged period of normalcy. If a determination is made in the negative that a

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FIG. 8 between times T3-T4. When the interval has elapsed data transmission to the central office may be terminated. Control is then passed to decision 1018 in which a determination is made as to whether a reset of limit request has been sent from the central office to the remote site portable patient monitor. These new limits may be automatically generated at the central office or may be input by a doctor at the central office. They may be appropriate when the patient needs to be more closely monitored. If this determination is in the affirmative then control is passed to process 1020 in which the limit memory is reset. Control is then returned to process 1000 discussed above. Alternately if in decision step 1018 a determination is made that no physician reset of the reprogrammable limits is requested, then control is directly returned to process 1000. The methods outlined above in processes 1000-1018 have the benefit of minimizing the communications between the central office and the remote site while assuring that critical detailed patient data is transmitted to the central office in a timely manner. Because the data transmitted to the central office is time stamped, a full record of the patient's biometric parameters including normal and abnormal readings can be reconstructed from the received information.

FIG. 10B shows the processing connected with the central office in an embodiment of the invention. The process begins at decision step 1054 in which a determination is made as whether an alarm event has been detected and data is being received from the remote site. If that determination is in the affirmative then control is passed to process 1056 in which all the buffer data from the remote site plus a real time feed from that site is prepared for viewing by the health care professional.

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Control is then returned to process 1054 for the processing of the next event or alarm condition received from a remote site.

FIGS. 11-17 are process flow diagrams of the processes at the remote site for monitoring specific disease states according to an embodiment of the invention.

These processes can be downloaded from the central office as part of a management record or can be contained in the portable patient monitor and selected from a menu of options displayed on that monitor. Each of the following processes may be accompanied by additional processes to enhance the functionality of the patient monitoring system at the remote site. These additional processes include: authentication of patient identity, visual or still images of the patient, buffering of patient data, etc..

FIG. 11. Management of fluid balance:

Edema is an abnormal accumulation of fluid in the tissue spaces, cavities or joint capsules of the body that may cause swelling and pain in the affected area. A physician whose patient presents with a history of recurrent edema may wish to have the patient continuously monitored for early signs of fluid retention. A system for performing this monitoring is described in the process flow diagram of FIG. 11.

In process 1102 the patient is monitored by a device strapped to his or her ankle that can detect presence of, and relative change in the circumference of the ankle indicating edema. The signal from the monitoring device is then transmitted

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The patient at risk for hypoxia during sleep and/or sleep apnea wears a device to monitor oximetry and/or to detect respiratory airflow and/or chest wall excursions, as shown in process 1202. The signal from the device is then transmitted to the portable patient monitoring device or the PMC for processing. If necessary, the signal may be sent to a patient monitoring computer for processing using short range half duplex RF transmission, or some other means of transmission. Control then passes to process 1204. In process 1204 the signal from the monitoring device is compared against a specified range of values for the biometric parameters being monitored. Control is then passed to decision process 1206. In decision process 1206 a determination is made as to whether the signal from the monitor is within the specified range of values. If that determination is in the affirmative control returns to process 1204 for continued monitoring of the patient. If the determination is in the negative, e.g. that values exceed the specified range(s) then control is passed to process 1208. In process 1208 the patient is then awakened. Next, in step 1210, a central monitoring station (e.g. a remote monitoring nurse) is automatically notified of the patient's condition.

FIG. 13 Arrhythmia management:

Arrhythmia is any disturbance in the electrical rhythm of the heart. An arrhythmia is an unstable series of disturbances in heartbeats, and may be associated with serious medical conditions, such as congestive heart failure or myocardial

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data values are transmitted to the central monitoring station. As will be obvious to those skilled in the art ECG monitoring may also be used for detecting other conditions of the heart such as ischemia.

FIG. 14 Monitoring for exacerbations of airway disease.

Peak expiratory flow rate in a patient can be used as an indicator of serious
5 respiratory problems. For example, decreased peak expiratory flow rate can be
indicative of lung collapse, pneumonia, or pulmonary edema, as well as airway
disease such as asthma. Understandably, if the patient has airway disease, or is at
risk for airway disease, then the patient's physician would want to monitor the
patient's peak expiratory air flow. A system for monitoring peak air flow is
10 described in the process flow diagram of FIG. 14.

In step 1402, the patient is beckoned and prompted to use the peak
expiratory flow meter, once per day. Next, in step 1404, instructions are displayed
for the patient to use the spirometer or other peak flow sensor device. The peak flow
test is then performed, as indicated in step 1406. The signal from the device is then
15 transmitted to the portable patient monitoring system for processing. If necessary,
the signal may be sent to a patient monitoring computer for processing using short
range half duplex RF transmission, or some other wireless means of transmission.
The test value is thereby recorded, as shown in step 1408. Until the test has been
repeated three times, the patient will be directed to repeat the test, as indicated by

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generates a pulmonary symptom score and a pulmonary management plan based on the NIH Asthma Guidelines (NHLTPublication 97-4053, October 1997).

FIG. 15 Wound Assessment:

Patients with healing wounds need to be checked on a regular basis. This is for obvious reasons: improperly healing wounds can lead to serious infection, gangrene, and possibly even death. Especially in the context of post-operative care, wound assessments need to be performed on a periodic basis. Understandably, the patient's physician would want to monitor the patient's wound. A system for monitoring wound healing is described in the process flow diagram of FIG. 15.

In operation, the patient is prompted, at an appropriate frequency, to assess their wound through an appropriate video system, in process 1502. Such a video system is preferably a digital video system, to facilitate transmission and processing of the video images. The patient exposes their wound to the video system, and the image or images is recorded, as shown in step 1504. Next, in step 1506, the patient is prompted to assess the wound through measurements and symptoms. The measurements of the wound may be made in a variety of ways. In one embodiment, the diameter or circumference of the wound is measured with electronic calipers or a transparent template with circles arranged in "bull's eye" pattern laid over the wound. The evaluation of the wound may also be accomplished by pattern matching processes implemented on an electronic image of the wound obtained by a video or

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various body tissues. These difficulties can lead to fatigue, muscle atrophy, death of the affected tissue, and other life-threatening conditions. Understandably, the patient's physician will want to monitor the state of the patient's disease. A system for monitoring the patient is described in the process flow diagram of FIG. 16.

In process 1604, the patient is prompted twice a day (or at a different
5 frequency) to use a pulse oximeter to monitor his/her oxygen saturation (SaO_2).
Next, in process 1606, instructions for using the pulse oximeter are displayed. The
patient then performs the SaO_2 test, as shown in process 1608. The signal from the
pulse oximeter may be transmitted to the portable patient monitor or the PMC for
processing. The data may be sent to a patient monitoring computer for processing
10 using short range half duplex RF transmission, or some other wireless means of
transmission. The signal is then recorded, as shown in step 1610. Control is then
passed to decision process 1612. In decision process 1612 a determination is made
as to whether the SaO_2 value is within an acceptable range. If it is control is passed
to process 1624. If it is not control is passed to decision process 1614. In decision
15 process 1614 a determination is made as to whether this is the second test. If it is not
control is passed to process 1616 for a repeat of the test. Subsequently control
returns to process 1610. If alternately in decision process 1614 a determination is
made that the test has already been repeated, then the patient will be prompted to use
a different finger in process 1618 and the test will be repeated in process 1620. If
20 the signal value in the new finger is within an acceptable range as determined in
decision process 1622, then the results are stored in process 1624 for later

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provide feedback to the patient regarding disease management. FIG. 17 shows a process flow diagram of a system for managing a diabetic patient's disease.

In operation, the patient is prompted to perform a glucoscan using a blood glucose monitoring device, as shown in step 1702. Instructions on how the patient should use the device are displayed on the display of the portable patient monitor or PMC in process 1704. The device is then used by the patient to perform the test, and
5 determine the blood glucose level in process 1706. The signal from the glucose monitoring device may be transmitted to a patient monitoring computer for processing using short range half duplex RF transmission, or some other means of transmission. The signal is then recorded in process 1708. Control is then passed to
10 decision process 1710. In decision process 1710 a determination is made as to whether the signal value is within an acceptable range. If it is not then control is passed to process 1712 in which the system informs the patient what dose of insulin to take.

If, however, the blood glucose level is abnormally high or low, then control
15 is passed to process 1714 in which the patient is prompted to make a self-assessment. This may be accomplished by using a display menu or an audio question sequence followed by recording of responses. For example: "are you dizzy?", "are you febrile?", "are you thirsty?", etc., are questions the patients may be asked. In an alternate embodiment a menu lists alternatives in a linear scale, with
20 "best" and "worst" marked at opposing ends, whereupon the patient selects a point along the scale corresponding to their symptom state or states. Alternatively, the

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What is Claimed is:

- 1 1. A computer implemented method for managing the care of a subject with at
2 least one condition, and the method for managing comprising the acts of:
3 determining a protocol for monitoring the subject, the protocol including at
4 least one biometric parameter to be monitored and at least one response associated
5 therewith;
6 monitoring the at least one biometric parameter; and
7 executing the at least one response associated with the biometric parameter
8 when the biometric parameter is beyond a selected threshold.
- 1 2. The method of claim 1, wherein the selected threshold comprises at least one
2 of: a value, range of values, and a rate of change in a value.
- 1 3. The method of claim 1, wherein the determining act further comprises the
2 act of:
3 retrieving from among a plurality of disease protocol records a protocol
4 record for the at least one condition, and the protocol record containing at least one
5 biometric parameter to be monitored and at least one response associated therewith.
- 1 4. The method of claim 1, wherein the determining act further comprises the
2 acts of:

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3 retrieving from among a plurality of disease protocol records a protocol
4 record for the at least one condition, and the protocol record containing at least one
5 biometric parameter to be monitored, at least one time at which to monitor the
6 biometric parameter, and at least one response associated therewith.

1 8. The method of claim 1, wherein the determining act further comprises the
2 acts of:

3 retrieving from among a plurality of disease protocol records a protocol
4 record for the at least one condition, and the protocol record containing at least one
5 biometric parameter to be monitored, at least one time at which to monitor the
6 biometric parameter and at least one response associated therewith, and the at least
7 one response including a dosage of a medication; and

8 calculating an additional time at which to monitor the at least one biometric
9 parameter to obtain information about the medication.

1 9. The method of claim 1, wherein the subject is located at a first site and
2 wherein the determining act further comprises the acts of:

3 retrieving from among a plurality of disease protocol records at a
4 central office a protocol record for the at least one condition, and the protocol record
5 containing at least one biometric parameter to be monitored and at least one response
6 associated therewith;

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- 1 11. The method of claim 1, wherein the subject is located at a first site; and
2 wherein the determining act further comprises the acts of:
3 retrieving from among a plurality of disease protocol records a
4 protocol record for the at least one condition, and the protocol record containing at
5 least one biometric parameter to be monitored and at least one response associated
6 therewith, and the at least one response including training data associated with a
7 sensor for monitoring the at least one biometric parameter;
8 translating the protocol record to a management record, and the
9 management record including computer code for monitoring the biometric
10 parameter;
11 downloading the management record to a portable subject monitor at
12 the first site; and
13 wherein further the monitoring and executing acts are performed by the
14 portable subject monitor at the first site.

- 1 12. The method of claim 1, wherein the subject is located at a first site; and
2 wherein the determining act further comprises the acts of:
3 retrieving from among a plurality of disease protocol records a
4 protocol record for the at least one condition, and the protocol record containing at
5 least one biometric parameter to be monitored and at least one response associated
6 therewith, and the at least one response including questions for the subject;

-59-

1 14. The method of claim 1, wherein the subject is located at a first site, and
2 wherein the executing act further comprises the acts of:
3 detecting at the first site that the biometric parameter is beyond a selected
4 threshold;
5 sending from the first site to a second site, data on the biometric parameter
6 accumulated during the monitoring act.

1 15. The method of claim 14, further comprising the acts of:
2 receiving at the second site the data;
3 retrieving from among a plurality of disease protocol records at the second
4 site a protocol record for the at least one condition, and the protocol record
5 containing a display protocol for displaying the data; and
6 displaying the data in accordance with the protocol.

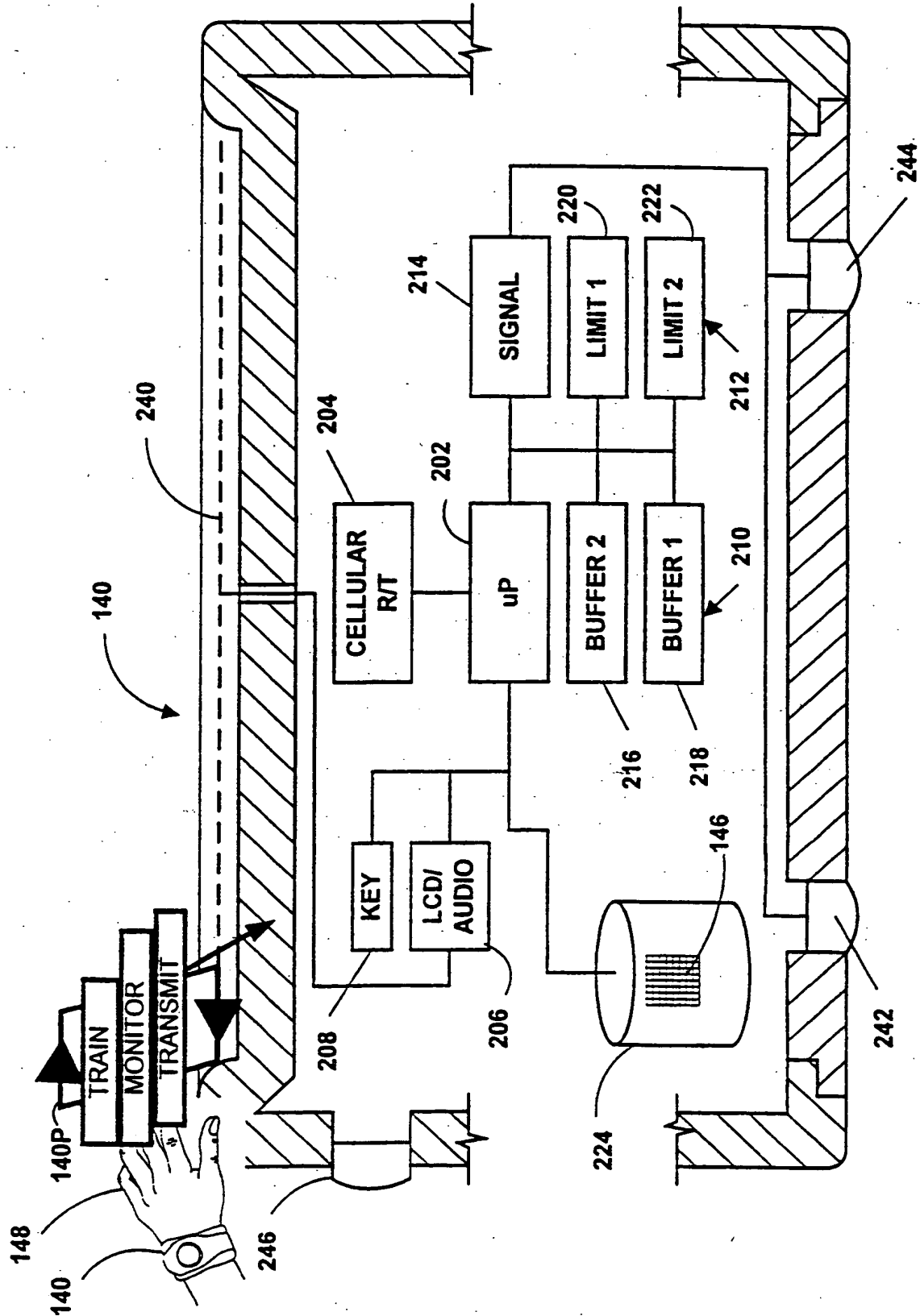


FIG. 2

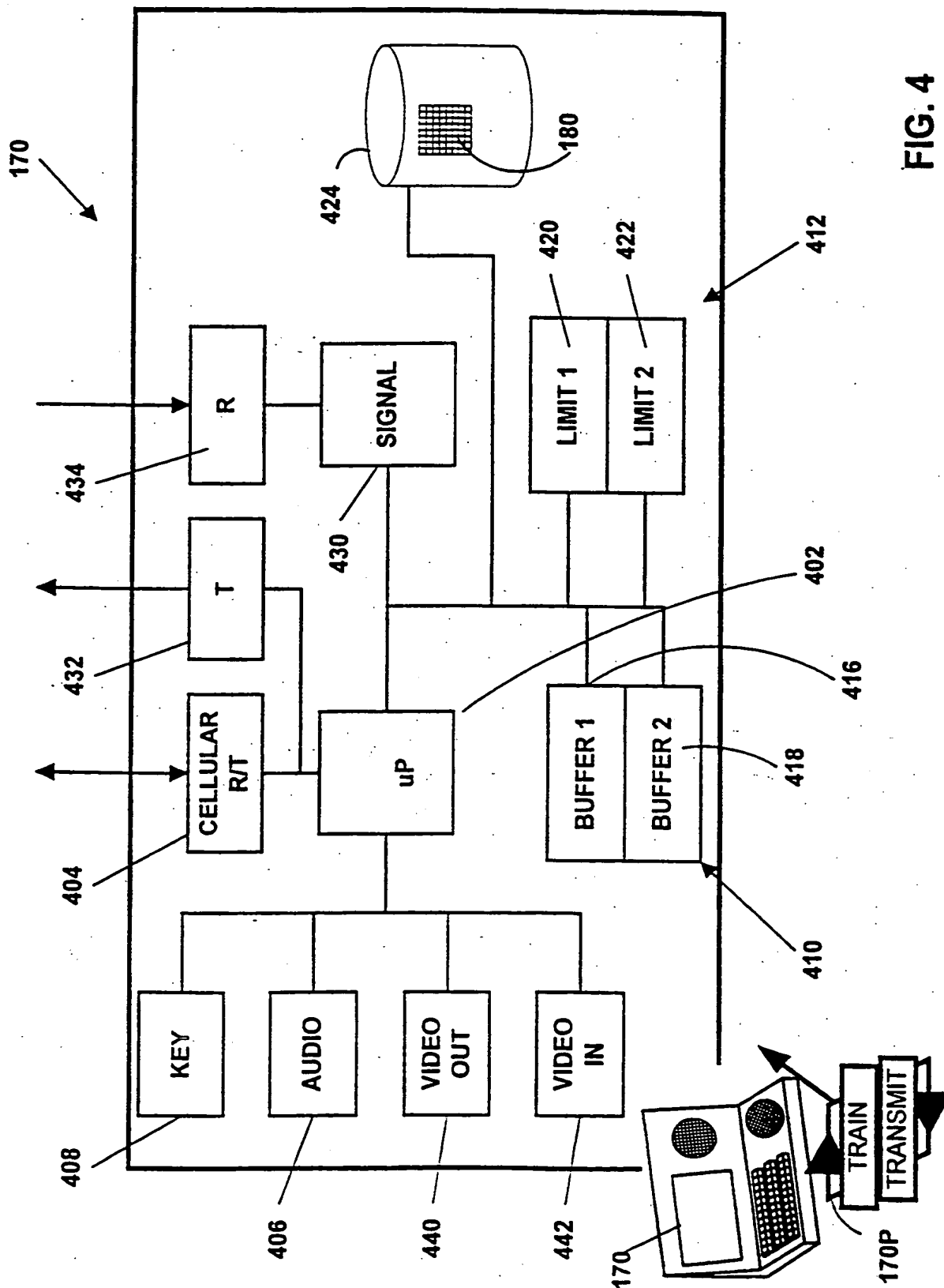


FIG. 4

600

INITIATING ORDERS	
NAME	John Smith
AGE	66
SEX	M
RESIDENCE	11 Oak St
INSURANCE	EVERLAST
PHYSICIAN	Dr. Fine
DIAGNOSES	Diabetes
MEDICATION	
Primary	Insulin
Route	Subcutaneous
Name	NPH
Freq	2x/Daily
Dose	20 Units
Type	
Route	
Name	
Freq	

610A

612A

614A

602

INITIATING ORDERS	
NAME	Lucile Jones
AGE	83
SEX	F
RESIDENCE	14 Clearwater
INSURANCE	PERMANENT
PHYSICIAN	Dr. Sloan
DIAGNOSES	Congestive Heart Failure
MEDICATION	
Primary	ACE Inhibitor
Route	Orally
Name	Captopril
Freq	4x/Daily
Dose	20 Mg
Type	
Route	
Name	
Freq	
Secondary	
Type	
Route	
Name	
Freq	

610B

612B

614B

604

INITIATING ORDERS	
NAME	Donna Hargst
AGE	38
SEX	F
RESIDENCE	144 Terrace
INSURANCE	ETERNITY
PHYSICIAN	Dr. Mills
DIAGNOSES	Hypertension
MEDICATION	
Primary	CA Ch. Blk.
Route	Orally
Name	Verapamil
Freq	4x/Daily
Dose	120mg Tablet
Type	
Route	
Name	
Freq	
Secondary	
Type	
Route	
Name	
Freq	

610C

612C

614C

FIG. 6

INITIATING ORDERS

702	PROTOCOL: CONGESTIVE HEART				CHF.?	730B
710B	PRIMARY BIOMETRIC	CONGESTION			TRAINING	732B
712B	FREQ./TIME	1 DAILY	9AM		RANDOM	734B
		Sensor A	Sensor B			
	714B	Weight	Edema			
		#>2lbs	#>15%	20Mg. Furosemide		
		#>5lbs	n/a	20Mg. Furosemide		
		#>5lbs	#>20%	Sensor C		
	716B	Sensor C				
		Blood Oxygen				
		#>92%		Maintain Regimen		
		90% <#<92%		Recheck SO2 12 Hrs		
		#<90%		Play Q&A & Notify Doc.		
718B	BASELINE BIOMETRIC	Enable				
720B	DISPLAY	Graph	x	y	z	
			Dose	Weight	Time	

CONGESTIVE HEART DISEASE PROTOCOL RECORD

FIG. 7B

FIG. 8B

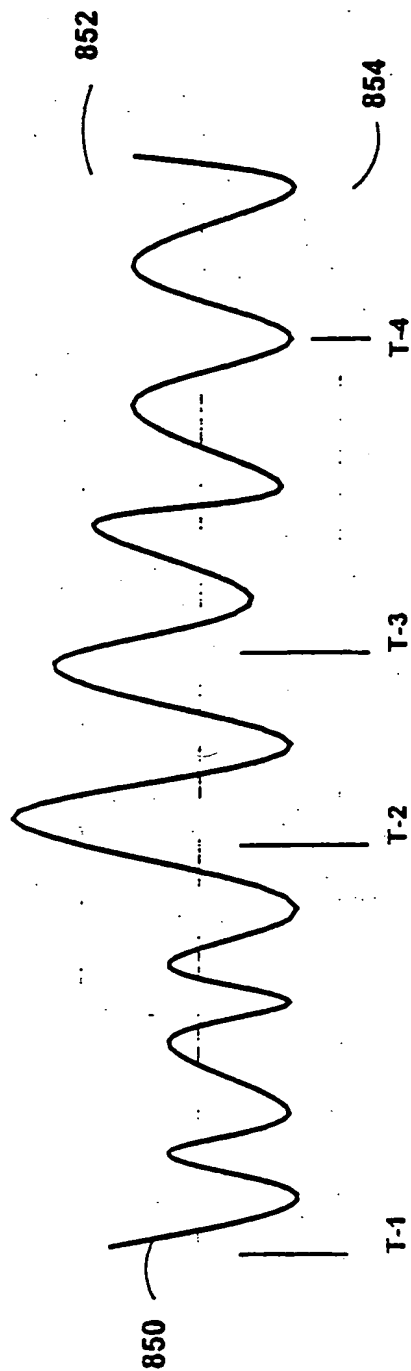
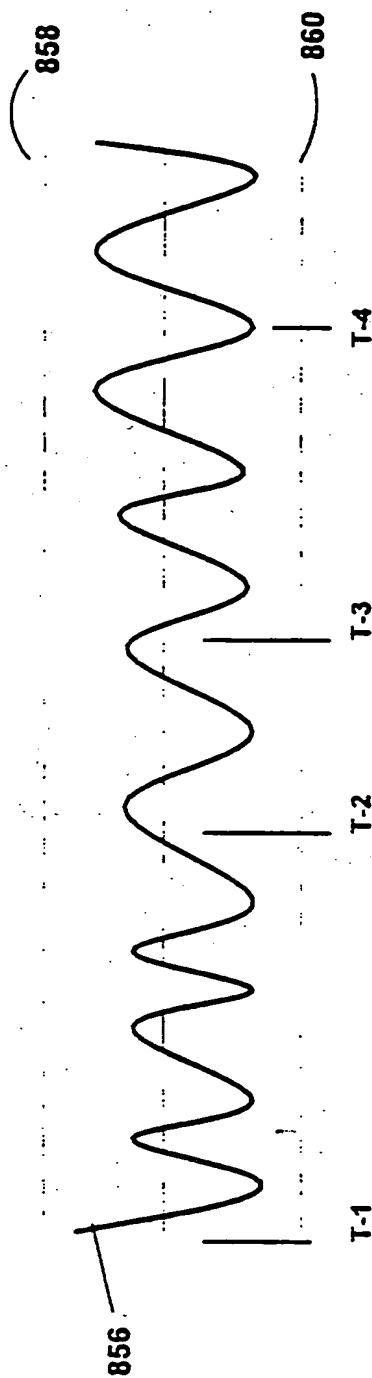


FIG. 8A



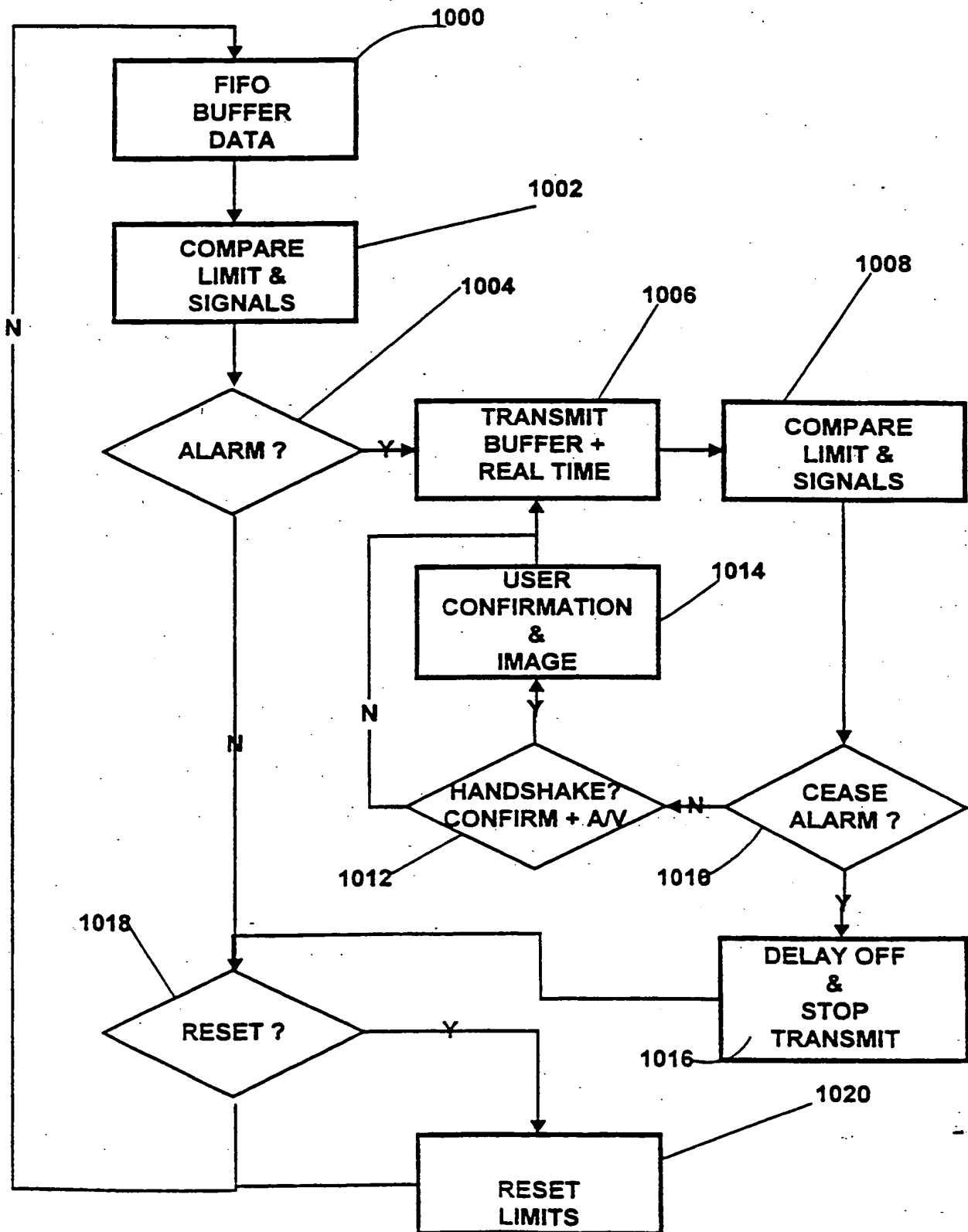


FIG. 10A

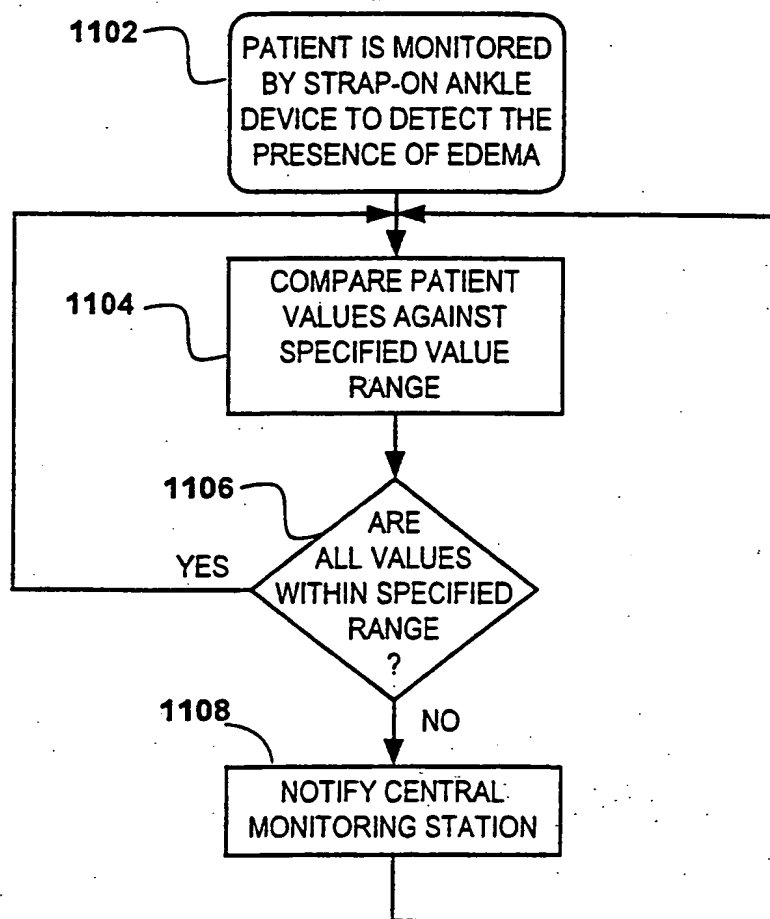


FIG. 11

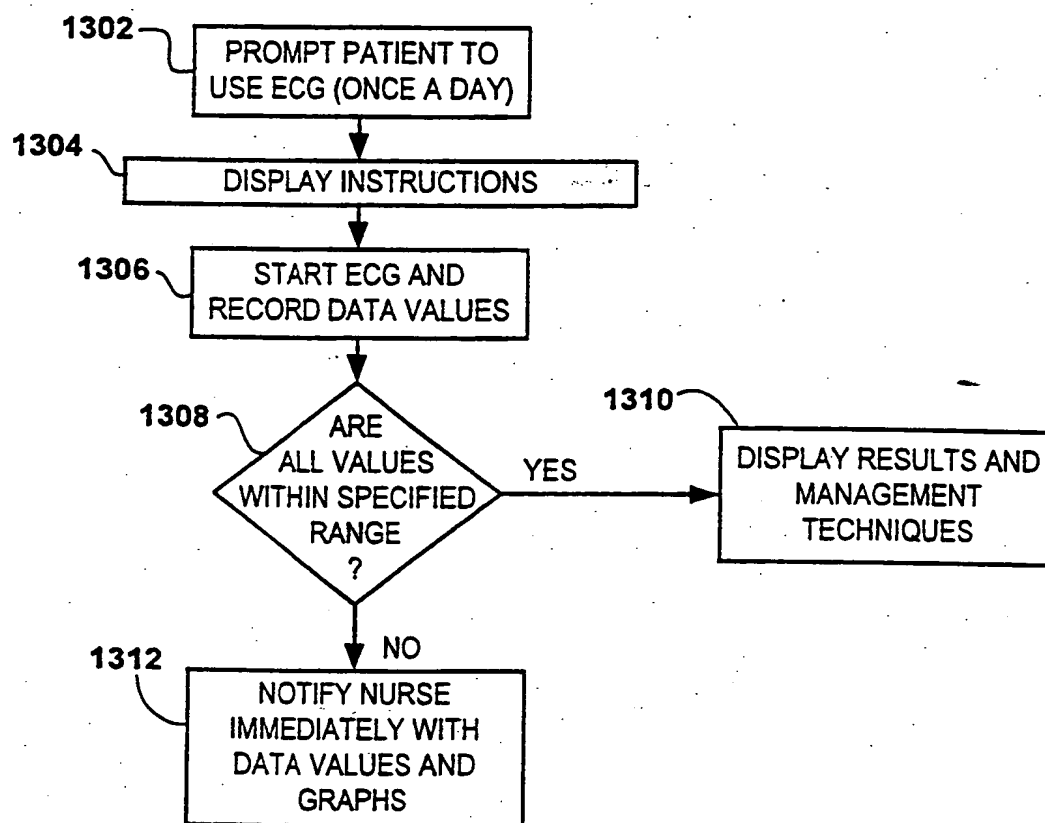


FIG. 13

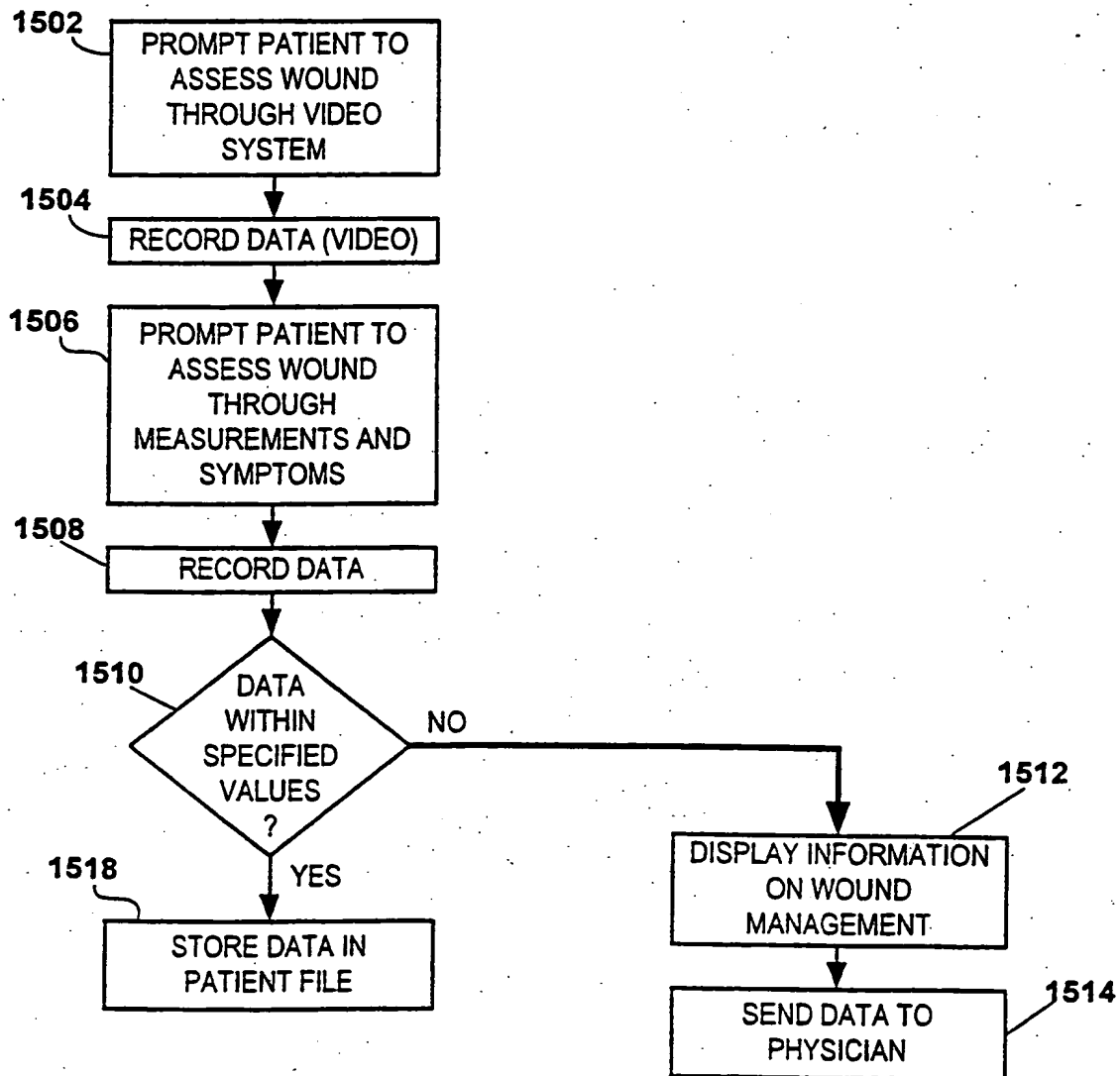


FIG. 15

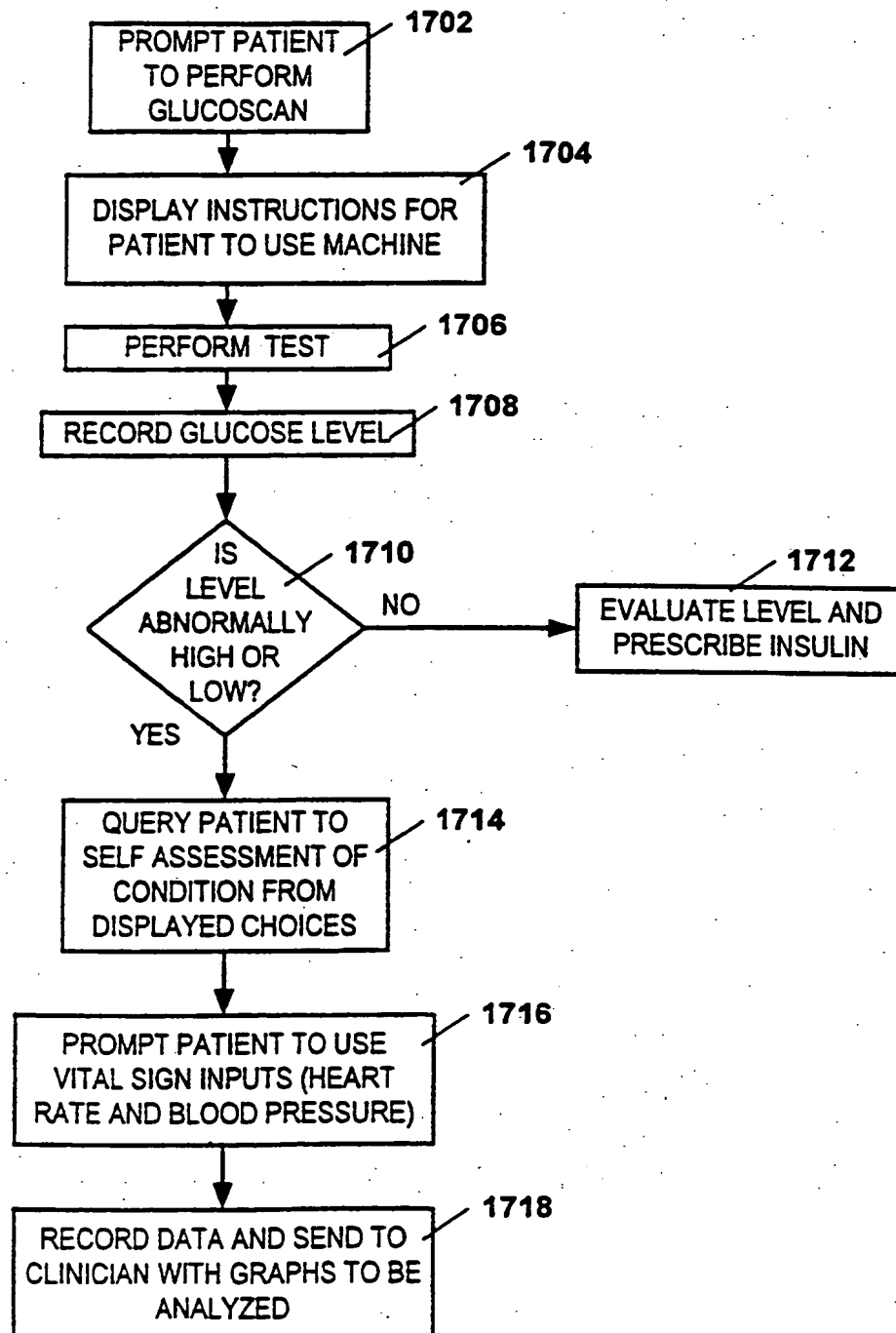


FIG. 17

INTERNATIONAL SEARCH REPORT

Int. l. Application No

PCT/US 98/08911

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 08910 A (COHEN KOPEL H) 21 March 1996 see page 5, line 28 - page 13, line 2 -----	1-15
A	WO 95 32480 A (SANDERS MATTHEW H ; ENACT PRODUCTS INC (US); TACKLIND CHRISTOPHER A) 30 November 1995 see page 8, line 21 - page 19, line 2; figures 1-10 -----	1-15



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

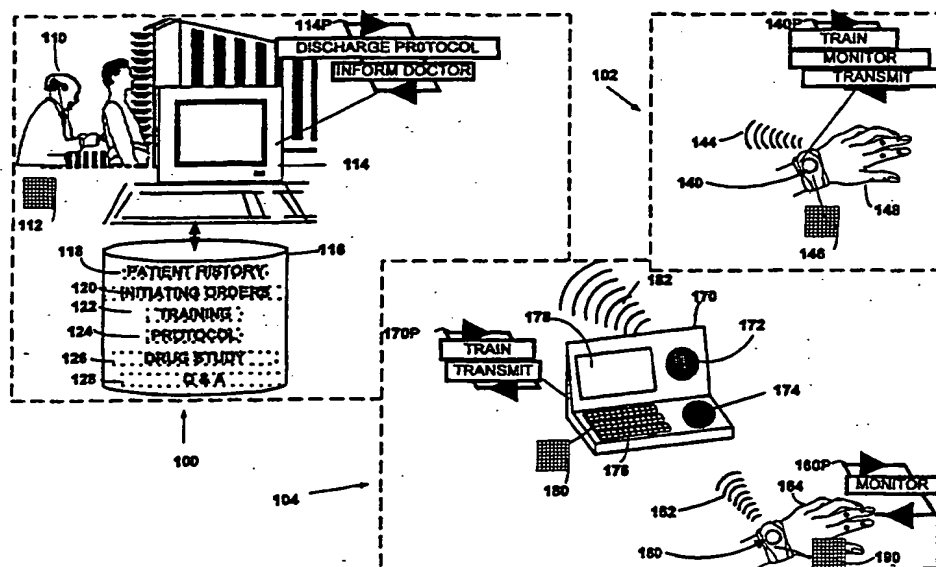
(51) International Patent Classification ⁶ : G06F 19/00		A1	(11) International Publication Number: WO 98/50873
			(43) International Publication Date: 12 November 1998 (12.11.98)
(21) International Application Number: PCT/US98/08911		(74) Agent: CARY, Charles, C.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).	
(22) International Filing Date: 1 May 1998 (01.05.98)			
(30) Priority Data: 60/045,436 2 May 1997 (02.05.97) US 60/081,369 10 April 1998 (10.04.98) US		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications US 60/045,436 (CIP) Filed on 2 May 1997 (02.05.97) US 60/081,369 (CIP) Filed on 10 April 1998 (10.04.98)		Published With international search report. With amended claims.	
(71) Applicant (for all designated States except US): CYBER-HEALTH, INC. [US/US]; 1614 Valmont Street, New Orleans, LA 70115 (US).		Date of publication of the amended claims: 30 December 1998 (30.12.98)	
(72) Inventors; and (75) Inventors/Applicants (for US only): WALKER, Cedric, F. [US/US]; 2619 Nashville Avenue, New Orleans, LA 70115 (US). KARP, Edward, W. [US/US]; 1614 Valmont Street, New Orleans, LA 70155 (US). FINE, Jonathan, M. [US/US]; 10 Bittersweet Road, Weston, CT 06856 (US).			

(54) Title: CYBER MEDICINE DISEASE MANAGEMENT

(57) Abstract

The subject health monitoring system is designed to supplement in an embodiment of the invention the health care efforts in caring for patients confined to their homes. The system may also be utilized within a facility such as a nursing home for monitoring patients within the home. The system integrates components distributed between a hospital and/or a central monitoring office to provide improved monitoring of these patients. The system provides for the translation of initiating orders into a computerized format. The system further provides for the programming of a patient monitoring unit at the remote site with the specific protocols consistent with the diagnoses of the doctor, as indicated on the initiating order. The system further provides for computerized

training and prompting of the patient to assure their compliance with the initiating orders. Additionally, the system provides for intelligent communication between the remote site and the central office when appropriate. The system provides for the transmission of relevant data from the remote site to the central office when a critical event occurs. The system also provides for notification and graphical presentment to the doctor of trending of the patients biometric parameters. The trending parameters computed and presented to the doctor are disease specific, thus making for a more timely response. Finally, the system provides for the accumulation of a statistically normalized database correlating various medications as to their efficacy, duration, and side effects.



AMENDED CLAIMS

[received by the International Bureau on 4 November 1998 (04.11.98);
new claims 16-25 added; remaining claims unchanged (5 pages)]

1 16. A patient monitoring device for managing the care of a subject at a first
2 site, and the patient monitoring device comprising:
3 a receiver for receiving a management record from a second site, and the
4 management record containing at least one biometric parameter of the subject to
5 be monitored and at least one response associated therewith;
6 a sensor to generate a signal corresponding to the at least one biometric
7 parameter of the subject; and
8 a recorder to record the signal; and
9 a first logic for executing the at least one response associated with the
10 biometric parameter when the biometric parameter is beyond a selected
11 threshold.

1 17. The patient monitoring device of claim 16, further comprising:
2 a transmitter for transmitting an event record to the second site and the
3 event record including the recorded signal for the at least one biometric
4 parameter; and
5 wherein the at least one response includes the transmission of the event
6 record to the second site.

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4 wherein the recorder records the signal at the at least one time.

1 22. The patient monitoring device of claim 16, further comprising:
2 a camera for obtaining at least one image of the subject; and
3 wherein the at least one response includes obtaining an image of the
4 subject.

1 23. A central control for monitoring a subject with a specific condition at a
2 first site and the central control comprising:
3 a plurality of disease protocol records including a protocol record for
4 the at least one condition, and the protocol record containing at least one
5 biometric parameter to be monitored, at least one response associated
6 therewith;
7 means for retrieving the protocol record for the at least one condition
8 from the plurality of disease protocol records;
9 a transmitter for transmitting the protocol record to the first site.

1 24. The central control of claim 23, further comprising:
2 a receiver for receiving an event record from the first site and the event
3 record including a recorded signal for the at least one biometric parameter; and
4 means for notifying a doctor of the receipt of the event record and for
5 displaying to a doctor the at least one biometric parameter.

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- 28 d) a first logic for executing the at least one response
29 associated with the biometric parameter when the biometric parameter is beyond
30 a selected threshold.
- 31 e) a transmitter for transmitting an event record to the
32 second site and the event record including the recorded signal for the at least
33 one biometric parameter; and
- 34 wherein the at least one response includes the transmission of the event
35 record to the second site.